

R E M A R K S

Claims 1-19 are pending in the present application. The following rejections remaining at issue and are set forth by number in the order in which they are addressed:

1. Claims 1-30 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 9-16 of U.S. Patent No. 6,015,833 in view of Cook et al. U.S. Patent No. 5,760,082; and
2. Claims 1-30 are rejected under 35 U.S.C. §103(a), as allegedly obvious over Cook et al. (U.S. Patent No. 5,760,082) in view of Cain et al. (WO97/18320) and Baltes et al. (U.S. 3,162,658) in further view of Nilsen et al. (U.S. 5,885,594);

Claims 1,4, 7, 10, 13 and 16 have been amended. Support for the amendments may be found in the specification at pages 22-25. Applicants believe that the amendments and remarks present herein traverse all of the Examiner's remaining rejections.

1. The Double Patenting Rejection Is Improper

Applicants contend that the double patenting rejection is not proper for the reasons stated in the prior Response and Amendment. Nevertheless, Applicants herein offer to submit a Terminal Disclaimer over the U.S. 6,015,833 upon the Examiner's indication of patentable subject matter in the instant application.

2. The Examiner Has Failed to Establish a *Prima Facie* Case of Obviousness

Claims 1-30 remain rejected under 35 U.S.C. §103(a) as allegedly being obvious under Cook et al. (U.S. Patent No. 5,760,082) in view of Cain et al. (WO97/18320) and Baltes et al. (U.S. 3,162,658) in further view of Nilsen et al. (U.S. 5,885,594) for the reasons made of record in the December 28, 2001, Office Action. Applicants must again respectfully disagree.

A *prima facie* case of obviousness requires the Examiner to cite a reference, or combination of references, that (a) discloses all of the elements of the claimed invention, (b) provides a suggestion or motivation to one of skill in the art to combine the elements to yield the claimed combination, and (c) provides a reasonable expectation of successfully carrying out the claimed combination. Failure to establish any one of the three requirements precludes a finding of a *prima facie* case of obviousness, and, without more, entitles the Applicants to

allowance of the claims at issue.¹ In addressing this rejection, Applicants focus on the independent claims since the non-obviousness of independent claims necessarily leads to the non-obviousness of the claims dependent thereon.²

A. No Motivation To Combine The References

When applying 35 U.S.C. §103, the references must be considered as whole. References cannot be considered collectively until the Examiner points to some motivation to combine the cited references.³ Applicants submit that the Examiner has yet to provide sufficient evidence of a suggestion or motivation for making the cited combination. The Examiner states that:

Cook teaches a food product containing conjugated linoleic acids, Cain et al. teaches that it is well known in the art that antioxidants, such as vitamin E or BHT, is known to be useful in food products containing conjugated linoleic acid compounds Baltes teaches that isomerization of linoleic acid compounds to conjugated linoleic acid compounds by alcoholate catalysts. . . . Therefore, it would have been *prima facie* obvious to a person of ordinary skill in the art . . . to incorporate conjugated linoleic acid derivatives, including esters, as well as antioxidant in food product [sic].⁴

Simply reciting elements from the Cook and Cain references and then citing to Baltes et al., as allegedly providing suitable conjugation methods as used in the presently claimed invention is insufficient to establish a valid *prima facie* case of obviousness.

Cook et al. describe production of conjugated linoleic acids using KOH or NaOH and ethylene glycol (see e.g., *col. 2, ll. 20-27* and *col. 5, ll. 38-46*). However, there is NO suggestion in Cook et al., nor in any of the references, of **methods** for producing food products containing conjugated linoleic acid products wherein the compositions are derived from conjugated linoleic acid esters produced by treating the esters with an alcoholate catalyst as are presently being claimed.

¹ See, e.g., *Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990).

² §MPEP 2143.03.

³ *Hodash v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143, n. 5, 229 USPQ 182, 187, n.5 (Fed. Cir. 1986).

⁴ December 28, 2001, Office Action, pp. 3-4.

Furthermore, when one examines the Baltes et al. reference, it is clear that there is no motivation to combine Cook, Cain, or Nilsen with Baltes to produce the presently claimed invention. In particular, Baltes et al. describe methods for producing conjugated linoleic acids described as being "valuable industrial products" for use in formation of "light colored polymers," for use as "ingredients of lacquers or coating compositions" or as "ingredients of plasticizers" and as "reaction components in the preparation of resins" (Baltes et al., *col. 9, ll. 47-60*). As such, the Baltes reference is directed to the production of substitutes for tung oil that are not suitable for consumption. The tung oil substitutes described in Baltes et al., are intended for industrial uses such as for drying oils, varnishes, and lacquers. Consequently, Baltes et al., describes methods for producing toxic oil substitutes for non toxic oils (tung oil). Nothing in the Baltes et al. reference teaches or suggest the desirability--or even applicability--of using the methods disclosed therein to produce food products.

Indeed, in view of the toxic products described in Baltes et al., the reference strongly **teaches away** from CLA compositions for suitable for oral consumption--let alone food products made by the claimed methods--even if viewed together with the other cited references.⁵ "A reference may be said to teach away when a person of ordinary skill, upon [examining] the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant."⁶

⁵ Baltes et al. *col. 9, ll. 46-61* teach that:

The compounds of the conjugated fatty acids obtained by the method of this invention, or mixtures containing these compounds, are valuable industrial products which can be used in many ways. For instance their polymerization by heating takes place at a very fast rate and therefore, the products can be converted into light colored polymer compounds by moderate heating, e.g., 260-280°C. The polymers thus formed can be used as ingredients of lacquers or coating compositions in conventional manner. Furthermore the conjugated fatty acids compounds of this invention can be used as ingredients of plasticizers for organic plastic materials, and as reaction components in the preparation of resins, such as alkyd resins or maleinate resins, in conventional manner.

⁶ *In re Para-Ordnance Manufacturing v. SGS Importers International*, 37 USPQ2d 1237, 1241 (Fed. Cir. 1995) (quoting *In re Gurley*, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994).

Accordingly, it is not proper to combine Baltes et al. with the other references because there is a lack of motivation for making this combination. This argument is supported by the previously submitted Declaration of Dr. Asgeir Sæbo. As detailed in the Sæbo Declaration, none of the references teach or suggest using CLA isomerized with alcoholate catalysts in food products. Furthermore, as explained by Dr. Sæbo, the Baltes patent discloses the use of oils with high levels of triunsaturated fatty acids. These oils are not generally suitable for the production CLA for oral consumption.

In the instant July 23, Final Office Action the Examiner again failed to provide evidence of a motivation or suggestion to combine the references, and in particular, to combine Baltes et al. with Cook, Cain, and Nilsen. The Examiner states that "Nowhere in Baltes [sic.] reference state that the method disclosed therein [sic.] only suitable for producing CLA solely for coating application [sic.]" Final Office Action, p. 4. The Examiner CANNOT contort the absence of a particular statement in a cited reference as somehow constituting evidence of that very same statement. Indulging in the Examiner's logic Applicants note that there would be an incentive for Examiner's to find a combination of references that are silent on a particular claim element and then force the Applicants to rebut a teaching that does not exist. The Examiner's arguments CANNOT stand under the Federal Circuit's precedent.

A recent Federal Circuit case explicitly discusses the standards for establishing motivation to combine. (*See, In re Lee*, 277 F.3d 1338 (Fed. Cir. 2002)). Specifically, the Federal Circuit held that:

The factual inquiry whether to combine references must be thorough and searching. It must be based on **objective evidence** of record. **This precedent has been reinforced in myriad decisions, and cannot be dispensed with.**⁷

Furthermore, an Examiner may not simply rely on conclusory statements even for what they think might be common sense or well known in the art:

The 'common knowledge and common sense' on which the Board relied in rejecting Lee's application are not the specialized knowledge and expertise contemplated by the Administrative Procedure Act. Conclusory statements such as those here provided do not fulfill the agency's obligation. This court explained in *Zurko*, 258 F.3d at 1385, 59 USPQ2d at 1697 that 'deficiencies of the cited references cannot be remedied by

⁷ *See, In re Lee*, 277 F.3d 1338, 1344 (Fed. Cir. 2002); internal citations omitted; emphasis added.

the Board's general conclusions about what is 'basic knowledge' or 'common sense.' The Board's findings must extend to all material facts and must be documented on record, lest the 'haze of so-called expertise' acquire insulation from accountability. 'common knowledge and common sense,' even if assumed to derive from the agency's expertise, do not substitute for authority when the law requires authority.⁸

The majority of the claims pending in this application are method claims, not composition claims. Applicants note that the Examiner has apparently failed to take into consideration the fact the conjugated linoleic acid produced by the methods of the present invention differ in composition from other conjugated linoleic acid products. These differences are claimed, for example, in Claims 25-30 and described in the Specification at pages 18 and 19.

For the reasons stated above, Applicants respectfully submit that a *prima facie* case of obviousness has not been established and therefore respectfully request that this rejection be withdrawn.

B. References Do Not Teach All Of The Elements Of The Claims

Applicants have amended the claims to require that the CLA compositions are treated so that less than 5 ppm volatile organic materials are present. Such treatment methods are disclosed in the specification at pages 22-25. The cited prior art references do not teach or suggest these treatment methods or alternative treatment methods for producing the food-grade quality CLA of the present invention. For example, as stated in paragraph 6 of the previously submitted Sæbo Declaration, the starting materials used by Baltes produced compositions that were unstable and would have high levels of breakdown products. Because the cited references do not teach each element of the claims, the claims must be passed to allowance.

C. The Cited References Do Not Provide Reasonable Expectation Of Success

The cited references do not provide a reasonable expectation of successfully for obtaining the claimed methods and compositions.

⁸ *Id.* at 1344-1345.


The Federal Circuit has held that "obvious to experiment" is not the standard for obviousness.⁹ The Court in *In re Dow Chemical* made it very clear that one must determine whether "the prior art would have suggested to one of ordinary skill in the art that this process **should** be carried out and **would** have a reasonable likelihood of success, viewed in light of the prior art."¹⁰

Applicants submit that one skilled in the art would not believe that a reasonable expectation of success existed for arriving at the claimed invention. As taught in the specification, the performance of a number of procedures was necessary to ensure that the resulting CLA compositions would have low levels of volatile organic compounds. The cited prior art does not recognize the problem of volatile organic compounds, nor does it provide solutions capable of resolving the problem. As such, the cited references do not provide a reasonable expectation of success in arriving at the claimed invention. Therefore, the claims should be passed to allowance.

C O N C L U S I O N

All grounds of rejection and objection of the Final Office Action of July 23, 2002, having been addressed, reconsideration of the application is respectfully requested. It is respectfully submitted that the invention as claimed fully meets all requirements and that the claims are worthy of allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

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J. Mitchell Jones
Registration No. 44,174

MEDLEN & CARROLL, LLP
101 Howard Street, Suite 350
San Francisco, California 94105

⁹ *In re Dow Chemical*, 5 USPQ2d 1529, at 1532 (Fed. Cir. 1988).

¹⁰ *Id.* at 1531; emphasis added.

APPENDIX 1

**Marked-up version of the rewritten, added, and/or cancelled claims pursuant to 37
C.F.R. §1.121(c)(1)(ii)**

1. (Amended Twice) A method for producing a food product containing conjugated linoleic acid esters comprising:
 - a) providing:
 - i) linoleic acid esters,
 - ii) an alcoholate catalyst,
 - iii) a foodstuff;
 - b) treating said linoleic acid esters with said alcoholate catalyst to provide conjugated linoleic acid esters; [and]
 - c) treating said conjugated linoleic acid esters under conditions such that the volatile organic compound content of said conjugated linoleic acid esters is less than 5 ppm;
 - [c]d) combining said foodstuff with said conjugated linoleic acid esters from step (c) to produce a food product.

4. (Amended Twice) The method of Claim 1, wherein step (c) further [comprising] comprises treating said conjugated linoleic acid esters with an adsorbing agent, providing an antioxidant and combining said antioxidant with said conjugated linoleic acid esters and said foodstuff in step (b) to produce said food product.

7. (Amended Twice) A method for producing a food product containing conjugated linoleic acid comprising:
 - a) providing:
 - i) linoleic acid esters,
 - ii) an alcoholate catalyst,
 - iii) a foodstuff;
 - b) treating said linoleic acid esters with said alcoholate catalyst to provide conjugated linoleic acid esters;

- c) treating said conjugated linoleic acid esters to provide conjugated linoleic acid;
- and
- d) treating said conjugated linoleic acid esters under conditions such that the volatile organic compound content of said conjugated linoleic acid esters is less than 5 ppm;
- [d]e) combining said foodstuff with said conjugated linoleic acid esters from step (c) to produce a food product.

10. (Amended Twice) The method of Claim 7, wherein step (d) further [comprising] comprises treating said conjugated linoleic acid esters with an adsorbing agent, providing an antioxidant and combining said antioxidant with said conjugated linoleic acid and said foodstuff in step (b) to produce said food product.

13. (Amended Twice) A method for producing a food product containing conjugated linoleic acid triglycerides comprising:

- a) providing:
- i) linoleic acid esters,
 - ii) an alcoholate catalyst, and
 - iii) a foodstuff; and
- b) treating said linoleic acid esters with said alcoholate catalyst to provide conjugated linoleic acid esters;
- c) incorporating said linoleic acid esters into triglycerides to provide triglycerides containing conjugated linoleic acid moieties; and
- d) treating said triglycerides containing conjugated linoleic acid moieties under conditions such that the volatile organic compound content of said triglycerides containing conjugated linoleic acid moieties is less than 5 ppm;
- [d]e) combining said foodstuff with said triglycerides containing conjugated linoleic acid moieties from step (c) to produce a food product.

16. (Amended Twice) The method of Claim 13, wherein step (d) further [comprising] comprises treating said triglycerides containing conjugated linoleic acid moieties with an

adsorbing agent, providing an antioxidant and combining said antioxidant with said triglycerides and said foodstuff in step (b) to produce said food product.

APPENDIX 2
Clean Version Of The Entire Set Of Pending Claims

1. (Amended Twice) A method for producing a food product containing conjugated linoleic acid esters comprising:
 - a) providing:
 - i) linoleic acid esters,
 - ii) an alcoholate catalyst,
 - iii) a foodstuff;
 - b) treating said linoleic acid esters with said alcoholate catalyst to provide conjugated linoleic acid esters;
 - c) treating said conjugated linoleic acid esters under conditions such that the volatile organic compound content of said conjugated linoleic acid esters is less than 5 ppm;
 - d) combining said foodstuff with said conjugated linoleic acid esters from step (c) to produce a food product.

2. The method of Claim 1, wherein said linoleic acid esters are derived from oils selected from the group consisting of safflower, sunflower, and corn oil.

3. (Amended once) The method of Claim 1, wherein said alcoholate catalyst is selected from the group consisting of sodium methylate, potassium methylate, sodium ethylate, and potassium ethylate.

4. (Amended Twice) The method of Claim 1, wherein step (c) further comprises treating said conjugated linoleic acid esters with an adsorbing agent, providing an antioxidant and combining said antioxidant with said conjugated linoleic acid esters and said foodstuff in step (b) to produce said food product.

5. (Amended Once) The method of Claim 4, wherein said antioxidant is selected from the group consisting of α -tocopherol, β -tocopherol, lecithin, ascorbylpalmitate, and BHT.

6. (Amended Twice) The food product produced according to the method of Claim 1, further comprising an antioxidant selected from the group consisting of lecithin, ascorbylpalmitate, and BHT.

7. (Amended Twice) A method for producing a food product containing conjugated linoleic acid comprising:

- a) providing:
 - i) linoleic acid esters,
 - ii) an alcoholate catalyst,
 - iii) a foodstuff;
 - b) treating said linoleic acid esters with said alcoholate catalyst to provide conjugated linoleic acid esters;
 - c) treating said conjugated linoleic acid esters to provide conjugated linoleic acid;
- and
- d) treating said conjugated linoleic acid esters under conditions such that the volatile organic compound content of said conjugated linoleic acid esters is less than 5 ppm;
 - e) combining said foodstuff with said conjugated linoleic acid esters from step (c) to produce a food product.

8. The method of Claim 7, wherein said linoleic acid esters are derived from oils selected from the group consisting of safflower, sunflower, and corn oil.

9. (Amended once) The method of Claim 7, wherein said alcoholate catalyst is selected from the group consisting of sodium methylate, potassium methylate, sodium ethylate, and potassium ethylate.

10. (Amended Twice) The method of Claim 7, wherein step (d) further comprises treating said conjugated linoleic acid esters with an adsorbing agent, providing an antioxidant and combining said antioxidant with said conjugated linoleic acid and said foodstuff in step (b) to produce said food product.

11. (Amended Once) The method of Claim 10, wherein said antioxidant is selected from the group consisting of α -tocopherol, β -tocopherol, lecithin, ascorbylpalmitate, and BHT.

12. (Amended Twice) The food product produced according to the method of Claim 7, further comprising an antioxidant selected from the group consisting of lecithin, ascorbylpalmitate, and BHT.

13. (Amended Twice) A method for producing a food product containing conjugated linoleic acid triglycerides comprising:

- a) providing:
 - i) linoleic acid esters,
 - ii) an alcoholate catalyst, and
 - iii) a foodstuff; and
- b) treating said linoleic acid esters with said alcoholate catalyst to provide conjugated linoleic acid esters;
- c) incorporating said linoleic acid esters into triglycerides to provide triglycerides containing conjugated linoleic acid moieties; and
- d) treating said triglycerides containing conjugated linoleic acid moieties under conditions such that the volatile organic compound content of said triglycerides containing conjugated linoleic acid moieties is less than 5 ppm;
- e) combining said foodstuff with said triglycerides containing conjugated linoleic acid moieties from step (c) to produce a food product.

14. The method of Claim 13, wherein said linoleic acid esters are derived from oils selected from the group consisting of safflower, sunflower, and corn oil.

15. (Amended once) The method of Claim 13, wherein said alcoholate catalyst is selected from the group consisting of sodium methylate, potassium methylate, sodium ethylate, and potassium ethylate.

16. (Amended Twice) The method of Claim 13, wherein step (d) further comprises treating said triglycerides containing conjugated linoleic acid moieties with an adsorbing agent, providing an antioxidant and combining said antioxidant with said triglycerides and said foodstuff in step (b) to produce said food product.

17. (Amended Once) The method of Claim 16, wherein said antioxidant is selected from the group consisting of α -tocopherol, β -tocopherol, lecithin, ascorbylpalmitate, and BHT.

18. (Amended Twice) The food product produced according to the method of Claim 13, further comprising an antioxidant selected from the group consisting of lecithin, ascorbylpalmitate, and BHT.